ATRIO HEALTH PLANS

Urothelial Carcinoma
Padcev (Enfortumab Vedotin-ejfv) J9177
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	Date Requested _____
	Requestor _____ Clinic name: _____ Phone / Fax

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug ☐ Self-administered	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION DOES NOT GUARANTEE PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Urothelial Carcinoma PA

Drug Name(s):

PADCEV **ENFORTUMAB VEDOTIN-EJFV**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. **Drug meets the following utilization management criteria:**
    a. Urothelial Carcinoma – Bladder Cancer
        i. Used as a single agent when used as subsequent therapy following platinum-containing chemotherapy and prior treatment with a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor or when used as subsequent therapy for members who are ineligible for cisplatin-containing chemotherapy for any of the following:
            1. Stage II disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with concurrent chemoradiotherapy. radiotherapy alone or transurethral resection of bladder tumor (TURBT); or
            2. Locally advanced or metastatic disease; or
            3. Metastatic or local recurrence post-cystectomy; or
            4. Muscle invasive local recurrence or persistent disease in a preserved bladder; or
    b. Urothelial Carcinoma – Primary Carcinoma of the Urethra
        i. Used as a single agent when used as subsequent therapy following platinum-containing chemotherapy and prior treatment with a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor or when used as subsequent therapy for members who are ineligible for cisplatin-containing chemotherapy; or
    c. Urothelial Carcinoma – Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate
        i. Used as a single agent when used as subsequent therapy following platinum-containing chemotherapy and prior treatment with a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor or when used as subsequent therapy for members who are ineligible for cisplatin-containing chemotherapy.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
    - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
    - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

- **N/A**

Prescriber Restrictions:

- Oncology or related specialty

Coverage Duration:

Approval will be for 6 months

FDA Indications:

- Urothelial carcinoma, Metastatic or locally advanced, after PD-1 or PD-L1 inhibitor and platinum-containing chemotherapy or in patients ineligible for CISplatin-containing chemotherapy and have previously received 1 or more prior lines of therapy, as monotherapyView additional information.
- Urothelial carcinoma, Metastatic or locally advanced, ineligible for CISplatin-containing chemotherapy, in combination with pembrolizumab

Off-Label Uses:

- N/A

Age Restrictions:

- Safety and effectiveness have not been established in pediatric patients

Other Clinical Consideration:

- N/A

Resouces:

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